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Patent and Trademark Office

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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/953,680 09/29/92 SHEPHERD

A UTSK: 142

HANTIS, K EXAMINER

25M1/0426

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ART UNIT PAPER NUMBER

2505

DATE MAILED: 04/26/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 12/20/94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-36 are pending in the application.
Of the above, claims are withdrawn from consideration.
2. ☐ Claims have been cancelled.
3. ☐ Claims are allowed.
4. ☒ Claims 1-36 are rejected.
5. ☐ Claims are objected to.
6. ☐ Claims are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ; filed on
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

LACK OF CORRESPONDENCE

The specification, claims and drawings are objected to under 37 CFR 1.117 in that there is a lack of correspondence between the specification claims and drawings.

The specification and drawings are silent as to the following items:

A) - generating a plurality of substantially monochromatic radiation wavelengths, each wavelength of an absorbance subset of said plurality of wavelengths having been selected by their ability to distinguish the constituent components-

B) each wavelength of a scattering subset of wavelengths having been selected to maximize the effects of radiation scattering.

Applicant is required to secure correspondence between the specification, claims and drawings. No new matter should be added.

112 REJECTION; SECOND PARAGRAPH

Claims 1-36 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

I) Claim 1 is unclear.

Lines 3-7 recite the following:

A) each wavelength of an absorbance subset of said plurality of wavelengths selected to minimize the effects of radiation scattering.

Lines 7-9 recite the following:

B) each wavelength of a scattering subset of said plurality of wavelengths having been selected to maximize the effects of radiation scattering.

Lines 11-13 recite the following:

C) irradiating a sample of unaltered whole blood of unknown composition with said plurality of radiation wavelengths through a depth of said sample to minimize radiation scattering by unaltered whole blood.

Lines 14-17 recite the following:

D) detecting intensities of said radiation wavelengths after passing through said depth of said sample at a distance from said sample and over a detecting area, both chosen to minimize the effects of radiation scattering.

Claim 1 contradicts itself and creates inconsistencies in that lines 3-7 recite to minimize the effects of radiation scattering, lines 7-9 recite to maximize the effects of radiation scattering, lines 11-13 recite to minimize radiation scattering

and lines 14-17 recite to minimize the effects of radiation scattering.

From the specification, it appears that the main purpose of Applicant's device is to minimize the effects of radiation scattering (see page 14, lines 27-34). Therefore lines 7-9 make no sense. Why would the wavelength be selected to maximize the effects of radiation scattering when the specification and lines 3-7, 11-13, and 14-17 recite that the wavelengths are selected to minimize the radiation scattering? What is Applicant claiming?

Claims 2-36 are rejected due to their dependency in their base claim.

FOUR DIFFERENT REJECTIONS

In summary, due to Applicant's arguments being contradictory in nature four different rejections; have been made, i.e. titled Rejection I, Rejection II, Rejection III, Rejection IV.

Rejection I pertains to Anderson et al having the components of Applicant's claimed device and having the claims of the instant Application being different from the claims of 07/313,911. Therefore, the Curtis reference stands.

Rejection II pertains to Anderson et al having the components of Applicant's claimed device and the claims of the instant application being the same as 07/313,911. Therefore, Res Judicata still stands, and the Curtis reference is not prior art.

Rejection III pertains to the Examiner's interpretation as to Applicant's true meaning of the subset phraseology argument and having the claims of the instant application being different from the claims of 07/313,911. (Thus, the Curtis reference).

Rejection IV pertains to the Examiner's interpretation as to Applicant's true meaning of the subset phraseology argument and having the claims of the instant application being the same as 07/313,911 (Thus Res Judicata).

REJECTION I

102 REJECTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 20-24, 26-27, 34-36 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Anderson et al.

Anderson specifically states in the abstract that the present study was made with an integrating sphere spectrometer (see fig. 1) and application of Twersky's theory for the multiple scattering of waves permitted separation of the effects of absorption and scattering and the light transmittance on nonhaemoglobin blood i.e. unaltered whole blood. It is shown that the relationship between light scattering and red-cell concentration is parabolic and that the absorption of light with the erythrocyte is the same as in a haemoglobin solution, i.e. altered whole blood. See pages 174-183 in regard to the molar extinction coefficients, and the plurality of substantially monochromatic wavelengths. Note that Anderson inherently has correction for calculated concentrations, since the results of Anderson would have no meaning without such a correction. (See page 180, last line of the first paragraph).

103 REJECTION

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 2-9, 11-19, 25, 28-33 rejected under 35 U.S.C. § 103 as being unpatentable over Anderson et al.

Anderson in an unaltered whole blood measurement system, fails to disclose the specific depth of the sample, the specific detecting area, the specific distance from the sample, the specific half aperture angle of radiation emanating from the sample, computing an error index, selecting a wavelength range for bilirubin or sulfhemoglobin, red blood cell scattering vector and non specific scattering vector.

At the time the invention was made, it would have been obvious to one with ordinary skill in the art to modify Anderson to incorporate the specifics cited above. The rationale for this modification would have arisen, since it is apparent that the depth of the sample, the detecting area, the distance from the sample, and the half aperture angle all have a specific effect on the overall-measurement and it is a matter of design engineering to select which depth, area distance, or angle is required for a particular outcome. Anderson specifically shows that for different depths, different wavelengths etc., different results occur. Thus, a specific relationship between all of the specifics cited above are well known and it is up to the person

conducting the measurement what specifies are required for that specific outcome to occur. As for the error index, bilirubin, sulfhemoglobin, red blood cell scattering and non specific scattering vectors, the same reasoning cited above applies. It is up to the person conducting the measurement, as to what specifics are required for that specific outcome to occur.

In regard to claims 12-15, see page 177, second to last line of the first paragraph.

102 REJECTION

Claims 1, 10, 20-21, 23-24, 26-27 and 34-36 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Curtis et al.

Curtis discloses the following:

- A) "generating .. blood"; See column 6, lines 25+.
- B) "irradiating .. blood"; See Figure 2
- C) "detecting ... components"; See figure 2
- D) "calculating ... wavelengths"; See columns 4-6

Note that Curtis' system compensates for dirt, turbidity of the sample, changes in the light source, scratches or other system variables which effect the absorbance output. Thus, minimization of radiation scattering are disclosed by Curtis (see columns 1-2).

103 REJECTION

Claims 11-19, and 29-33 are rejected under 35 U.S.C. § 103 as being unpatentable over Curtis.

Curtis, in an unaltered whole blood analysis system, disclose everything except selecting four radiation wavelengths.

At the time the invention was made, it would have been obvious to one with ordinary skill in the art to modify Curtis to incorporate the four wavelength of Applicant's device. The rationale for this modification would have arisen since Curtis selects two wavelengths so as to minimize error due to the variations in the oxygenation, deoxygenation of the blood. It would have been obvious to modify Curtis to select four wavelengths instead of two wavelengths since the four wavelengths are used for the same reasons two wavelengths are used, i.e. to reduce variations as cited above. Clearly, the interchangeability of selecting two or four wavelengths is apparent since both will produce a minimum error measurement as seen by Curtis.

REJECTION II

102 REJECTION

Claims 1, 10, 20-24, 26-27, and 34-36 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by clearly anticipated by Anderson et al.

Anderson specifically states in the abstract that the present study was made with an integrating sphere spectrometer (see fig. 1) and application of Twersky's theory for the multiple scattering of waves permitted separation of the effects of absorption and scattering and the light transmittance on nonhaemoglobin blood i.e. unaltered whole blood. It is shown that the relationship between light scattering and red-cell concentration is parabolic and that the absorption of light within the erythrocyte is the same as in a haemoglobin solution, i.e. altered whole blood. See pages 174-183 in regard to the molar extinction coefficients, and the plurality of substantially monochromatic wavelengths. Note that Anderson inherently has correction for calculated concentrations, since the results off Anderson would have no meaning without such a correction. (See page 180, last line of the first paragraph).

103 REJECTION

Claims 2-9, 11-19, 25 and 28-33 are rejected under 35 U.S.C. § 103 as being unpatentable over Anderson.

Anderson in an unaltered whole blood measurement system, fails to disclose the specific depth of the sample, the specific detecting area, the specific distance from the sample, the specific half aperture angle of radiation emanating from the sample, computing an error index, selecting a wavelength range for bilirubin or sulfhemoglobin, red blood cell scattering vector and non specific scattering vector.

At the time invention was made, it would have been obvious to one with ordinary skill in the art to modify Anderson to incorporate the specifics cited above. The rationale for this modification would have arisen, since it is apparent that the depth of the sample, the detecting area, the distance from the sample, and the half aperture angle all have a specific effect on the overall-measurement and it is a matter of design engineering to select which depth, area distance, or angle is required for a particular outcome. Anderson specifically shows that for different depths, different wavelengths etc., different results occur. Thus, a specific relationship between all of the specifics cited above are well known and it is up to the person conducting the measurements what specifies are required for the

specific outcome to occur. As for the error index, bilirubin, sulfhemoglobin, red blood cell scattering and nonspecific scattering vectors, the same reasoning cited above applies. It is up to the person conducting the measurement, as to what specifics are required for that specific outcome to occur.

In regard to claims 12-15, see page 177, second to last line of the first paragraph.

RES JUDICATA

Claims 1-2, 5-6, 9-21, 23-24, 26-27, and 29-36 are rejected under Res Judicata on the basis of an earlier adverse decision of the board of Appeals against the inventor on the same claim or a claim involving the same (See MPEP 706.03(w)).

REJECTION III

103 REJECTION

Claims 1, 10, 20-24, 26-27, and 34-36 are rejected under 35 U.S.C. § 103 as being unpatentable over Anderson et al. in view of Brown et al.

Anderson, in a whole unaltered blood measuring system, disclose everything except is vague as to the following:

A) measurements at different wavelengths to calculate several different constituents of blood.

Brown, in a blood measuring system, disclose item A above.

At the time the invention was made, it would have been obvious to one with ordinary skill in the art to modify Anderson to incorporate item A of Brown.

The rationale for this modification would have arisen for the following reason. It would have been apparent to incorporate item A of Brown in Anderson since Anderson suggests data-gathering at appropriate wavelengths to calculate three or more constituents of blood as seen on page 182, section 4.2 and it is well known to calculate several different constituents of blood at different wavelengths to provide specific data of interest as seen and taught by Brown.

103 REJECTION

Claims 2-9, 11-19, 25 and 28-33 are rejected under 35 U.S.C. § 103 as being unpatentable over Anderson-Brown.

The Anderson-Brown system fails to disclose the specific depth of the sample, the specific detecting area, the specific distance from the sample, the specific half aperture angle of radiation emanating from the sample, computing an error index,

selecting a wavelength range for bilirubin of sulfhemoglobin, red blood cell scattering vector and non specific scattering vector.

At the time the invention was made, it would have been obvious to one with ordinary skill in the art to modify the Anderson-Brown system to incorporate the specifics cited above. The rationale for this modification would have arisen, since it is apparent that the depth of the sample, the detecting area, the distance from the sample, and the half aperture angle all have a specific effect on the overall-measurement and it is a matter of design engineering to select which depth, area distance, or angle is required for a particular outcome. Anderson specifically shows that for different depths, different wavelengths etc., different results occur. Thus, a specific relationship between all of the specifics cited above are well known and it is up to the person conducting the measurement what specifies are required for that specific outcome to occur. As for the error index, bilirubin, sulfhemoglobin, red blood cell scattering and non specific scattering vectors, the same reasoning cited above applies. It is up to the person conducting the measurement, as to what specifics are required for that specific outcome to occur.

In regard to claims 12-15, see page 177, second to last line of the first paragraph.

Also, in regard to HbO_2 , Hbco etc and their error index; see columns 3-4 of Brown where specific calculations show changes in

optical densities and the molar extinction coefficients are derived so as to obtain the concentrations of four hemoglobin species.

In regard to claims 16-17; 31 Brown discloses that it is well known to measure for bilirubin from specific wavelength measurement - See column 1, lines 25+. From this teaching claims 18-19, 32-33 are apparent.

102 REJECTION

Claims 1, 10, 20-21, 23-24, 26-27 and 34-36 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Curtis et al.

Curtis discloses the following:

- A) "generating .. blood"; See column 6, lines 25+
- B) "irradiating ... blood"; See Figure 2
- C) "detecting ... components"; See figure 2
- D) "calculating .. wavelengths"; See columns 4-6

Note that Curtis' system compensates for dirt, turbidity of the sample, changes in the light source, scratches or other system variables which effect the absorbance output. Thus, minimization of radiation scattering are disclosed by Curtis (see columns 1-2).

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Curtis, in an unaltered whole blood analysis system, disclose everything except selecting four radiation wavelengths.

At the time the invention was made, it would have been obvious to one with ordinary skill in the art to modify Curtis to incorporate the four wavelength of Applicant's device. The rationale for this modification would have arisen since Curtis selects two wavelengths so as to minimize error due to the variations in the oxygenation, deoxygenation of the blood. It would have been obvious to modify Curtis to select four wavelengths instead of two wavelengths since the four wavelengths are used for the same reasons two wavelengths are used i.e. to reduce variations as cited above. Clearly, the interchangeability of selecting two or four wavelengths is apparent since both will produce a minimum error measurement as seen by Curtis.

REJECTION IV

103 REJECTION

Claims 1, 10, 20-24, 26-27, and 34-36 are rejected under 35 U.S.C. § 103 as being unpatentable over Anderson et al. in view of Brown et al.

Anderson, in a whole unaltered blood measuring system, disclose everything except is vague as to the following:

A) measurements at different wavelengths to calculate several different constituents of blood.

Brown, in a blood measuring system, disclose item A above.

At the time the invention was made, it would have been obvious to one with ordinary skill in the art to modify Anderson to incorporate item A of Brown.

The rationale for this modification would have arisen for the following reason. It would have been apparent to incorporate item A of Brown in Anderson since Anderson suggests data-gathering at appropriate wavelengths to calculate three or more constituents of blood as seen on page 182, section 4.2 and it is well known to calculate several different constituents of blood at different wavelengths to provide specific data of inherent as seen and taught by Brown.

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The Anderson-Brown system fails to disclose the specific depth of the sample, the specific detecting area, the specific distance from the sample, the specific half aperture angle of radiation emanating from the sample, computing an error index, selecting a wavelength range for bilirubin or sulfhemoglobin, red blood cell scattering vector and non specific scattering vector.

At the time the invention was made, it would have been obvious to one with ordinary skill in the art to modify the Anderson-Brown system to incorporate the specifics cited above. The rationale for this modification would have arisen, since it is apparent that the depth of the sample, the detecting area, the distance from the sample, and the half aperture angle all have a specific effect on the overall-measurement and it is a matter of design engineering to select which depth, area distance, or angle is required for a particular outcome. Anderson specifically shows that for different depths, different wavelengths etc., different results occur. Thus, a specific relationship between all of the specifics cited above are well known and it is up to the person conducting the measuring what specifies are required for that specific outcome to occur. As for the error index, bilirubin, sulfhemoglobin, red blood cell scattering and non

specific scattering vectors, the same reasoning cited above applies. It is up to the person conducting the measurement, as to what specifics are required for that specific outcome to occur.

In regard to claims 12-15, see page 177, second to last line of the first paragraph.

Also, in regard to HbO_2 , Hbco etc and their error index; see columns 3-4 of Brown where specific calculations show changes in optical densities and the molar extinction coefficients are derived so as to obtain the concentrations of four hemoglobin species.

In regard to claims 16-17; 31 Brown discloses that it is well known to measure for bilirubin from specific wavelength measurement - See column 1, lines 25+. From this teaching claims 18-19, 32-33 are apparent.

RES JUDICATA

Claims 1-2, 5-6, 9-21, 23-24, 26-27, and 29-36 are rejected under Res Judicata on the basis of an earlier adverse decision of the board of Appeals against the inventor on the same claim or a claim involving the same issue (See MPEP 706.03(w)).

APPLICANT'S ARGUMENTS CONSIDERED

Applicant's arguments filed Dec. 20, 1994 have been fully considered but they are not deemed to be persuasive.

RESPONSE TO APPLICANT'S ARGUMENTS

I. Applicant argues that the difference between the instant application and 07/313,911 are the following items:

A) the instant application claims - generating a plurality of substantially monochromatic radiation wavelengths, each wavelength of an absorbance subset of said plurality of wavelengths having been selected by their ability to distinguish the constituent components-

B) each wavelength of a scattering subset of said plurality of wavelengths having been selected to maximize the effects of radiation scattering.

Examiner's Response to item A above:

From the specification of the instant application, for instance (note that there are other examples throughout the specification) page 37, lines 5-10; these "subsets" (although this phraseology "subsets" cannot be found anywhere in the

specification) appears to be the selection of four to eight wavelengths - these being in the approximate range of (500-620nm See pages 18, 20, 24, 26-28, and 37).

Application 07/313,911 page 7, lines 14-16 refer to the selection of five wavelengths; these being 520, 560, 582, 598, 620 (nm).

Therefore, it appears that Applicant's "subset" phraseology of the instant application has the same meaning as the wavelengths disclosed in Application 07/313,911.

Therefore, Applicant's argument of difference between the two applications (instant and 07/313,911) is mute.

Examiner's Response to item B Above:

Item B makes no sense for the reasons cited in the 112 rejection above. Also, the whole phraseology of item B cannot be found in the instant specification. Therefore, Applicant's arguments to item B are mute.

II. Examiner's Response to the Applicant's response to the MPEP 200.06(b) cited in the Office Action of July 15, 1994.

Applicant's response is vague as to providing information as to why 07/313,911 was not identified earlier in the instant Application.

III. Applicant's arguments are inconsistent.

First, Applicant argues that the specification, claims and drawings of the instant Application are different from the claims of 07/313,911. Then Applicant argues that the Curtis reference cannot be applied as prior art due to its date of 9/26/89 being after the parent case (07/313,911) of 2/23/89. Second, Applicant argues that the Curtis reference supports the parent's (07/313,911) specification, i.e. inferring that the Curtis reference discloses the same material as the parent 07/313,911.

If the specification, claims, drawings of the instant application are different as Applicant argues than the filing date of the parent 07/313,911 would make the Curtis reference prior art since 07/313,911 is a CIP of the instant application. Thus, claims that are directed to the in-part part of the parent can be applied, regardless of the parent's filing date.

IV. Applicant argues that Anderson measures altered whole blood of known composition in that the blood is altered by Anderson separating the red blood cells from other components of whole blood.

Examiner's Response to IV Above:

Anderson states on page 173-174 that the purpose of the present study was to investigate the light-scattering and light absorbing properties of nonhaemolyged blood, i.e. undiluted whole blood; i.e. unaltered whole blood.

Anderson then continues to compare the haemoglobin i.e. altered, diluted blood to the nonhaemolysed blood (unaltered/undiluted whole blood) on pages 174, and 177-183. From Applicant's citation of page 177 and reading the Anderson as a whole, it appears that Applicant's citation is in reference to the hemolyzed blood that is used to compare with measurements of the nonhaemolysed blood.

Since the whole reference of Anderson is directed to measuring undiluted whole blood and comparing these results to the old art of measuring diluted blood, clearly Applicant's arguments that Anderson is measuring only hemolyzed blood is mute. Therefore, the rejections stand.

V. Applicant argues that the sample of blood tested by Anderson is not unknown since Applicant refers to page 177 again where the citation states fully oxygenated nonhaemolysed red cells suspended in isotonic suline. Applicant argues that the

cells are fully oxygenated, therefore it is known what composition is in the samples of blood.

Examiner's Response to item V.

First, the Examiner does not agree that this recitation is the only sample measured in Anderson's system. This sample appears to be the comparison sample and not the main samples measured. The comparison sample being altered blood being compared to Anderson's improvement over the prior art - the measuring of whole undiluted blood.

Second, Anderson does measure a known composition of whole unaltered blood and then creates a graph. This gives a calibration curve. Then, Anderson evaluates whole unaltered blood of unknown composition and compares this to the calibration curve.

Anderson, also, compares hemolyzed (altered) and nonhaemoalyzed (unaltered) samples (see page 178). Therefore, Anderson does measure the unknown composition of whole unaltered blood.

Also, note on page 178, under 3.3 that both types of blood - hemolyzed (diluted) and nonhaemolysed (undiluted) were measured and compared.

VI. Applicant argues that Anderson does not disclose the "subset" phraseology of claim 1.

Examiner's Response to item VI:

It appears from page 18, 20, 24, 26-28 and page 37 that these "subsets" appear to be the selection of four to eight wavelengths. These being in the range of approximately 500-620nm.

Anderson use wavelengths in the range from 500 to 620 nm.

Note that claim 1 does not specify a range and that its dependents specify range as disclosed Anderson.

VII. Applicant argues that Curtis does not disclose the following items:

- X) Curtis is not prior art
- Y) Curtis uses altered/diluted blood
- Z) The subset phraseology is not disclosed in Curtis

Examiner's Response to item X of VII above:

If Applicant's claims are different as Applicant argues then they seem to be directed to the in-part part of the parent 07/313,911. Therefore, Curtis can be applied as prior art.

Examiner's Response to item Y of VII above:

Curtis specifically states in column 1, lines 3-26 that the purpose of Curtis device is to prevent dilution of the blood which cause inaccuracies. Column 2, lines 50-55, column 4, lines 12-15 claim 24 recite specifically recite that the sample being measured is an "undiluted blood sample."

Examiner's Response to item Z of VII:

The phraseology "subset" appear to be directed to the selection of four to eight wavelengths. In application's specification these being in the range of approximately 500-620nm. See column 1, lines 45+; column 4, lines 5+; etc of Curtis.

VIII. Applicant argues that claims 2-9, 11-19, 25, 28-33 are not obvious.

Examiner's Response to VIII:

There is a specific relationship between all the specifics cited in the above claims. These relationships are all mathematically based and it is well known to manipulate data in

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order to give the results necessary as seen by Anderson, Curtis and Brown.

IX. Applicant argues that Anderson does not inherently correct for the effects of radiation scattering.

Examiner's Response to IX above:

Anderson must have a correction or else Anderson's results would be meaningless. Also, note that none of the claims use Applicant's phraseology as cited on page 14 under Section 5 of Applicant's Remarks of December 20, 1994.

Also, Applicant's does attest to Anderson having a correction in line 21 of page 14 of Applicant's Remarks of December 20, 1994.

DECLARATIONS

The Declarations of Mr. Nilsson and Mr. Oberg under 37 CFR 1.1132 have been considered but deemed mute due to the new rejections in reference to Brown.


The Declaration of Schmitt and Pittman under 37 CFR 1.132 have been entered considered but deemed mute since they argue that the curve-fitting techniques of Anderson are different from Applicant's device where these differences of techniques are not claimed in Applicant's claims. Also deemed mute to the new rejection reference to Brown.


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The Declaration of Shephard, under 37 CFR 1.132 has been considered but deemed mute since it has given little evidentiary value because it is not clear what the commercial success is attributed to because of the indefinite language used. Under 4. it states "the elements of at least Claim I." What else does it embody? Under 7 it states that technology disclosed and claimed and Exhibit B states Mr. Mountain has not seen a copy of the claims. It is not clear what the License agreement covers.

Any inquiry concerning this communication should be directed to K. Hantis at telephone number (703) 308-4801.


Hantis/tj
April 10, 1995


FRANK GONZALEZ
PRIMARY EXAMINER
GROUP 250